Remarks

In the Office Action mailed February 2, 2004, claims 1-42, 44 and 46-54 were rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement and under 35 U.S.C. § 112, second paragraph, for indefineteness. Claims 1, 25, and 26 were rejected under the doctrine of obviousness-type double patenting over claim 25 of U.S. Patent No. 5,736,119. Claims 37-40 were rejected under the doctrine of obviousness-type double patenting over claims 25 and 29-34 of U.S. Patent No. 5,846,741. Claims 1, 25 and 27 were rejected under the doctrine of obviousness-type double patenting over claim 41 of U.S. Patent No. 5,482,698. Claims 1-42, 44, and 46-54 were provisionally rejected under the doctrine of obviousness-type double patenting over claims 46, 52, 54-66, 69-95, 104, 108-127, 129, 134-153, 158, 164-166, 169, 204, 206, and 210 of co-pending U.S. Patent Application No. 10/361,026. The specific grounds for objection, and Applicants' response thereto, are set out in detail below.

Claims 1, 37, and 38 have been amended and claim 6 has been canceled. Claims 1-5, 7-42, 44, and 46-54 are pending for reconsideration, which is respectfully requested in view of the foregoing amendments and following remarks.

Rejection under § 112, first paragraph

Claims 1-42, 44 and 46-54 are rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not enable compositions for treating infectious diseases in a patient. Applicants respectfully traverse.

Applicants submit that one skilled in the art readily would be able to treat infectious diseases based on the teachings of the instant disclosure, by employing no more than routine experimentation. Nevertheless, without acquiescing in any way in the propriety of the rejection, Applicants have amended claims 1, 37, and 38 to delete the recitation of infectious disease causing agents thereby mooting the rejection. Accordingly, withdrawal of the rejection respectfully is requested.

Rejection under § 112, second paragraph

The Examiner alleges that claims 1-42, 44, and 46-54 are indefinite under 35 U.S.C. § 112, second paragraph. Specifically, the Examiner states that the term "(c) corresponding

enzymes and prodrug substrates", recited in claim 38 is ambiguous and that claims 1-42, 44, and 46-54 are ambiguous because one of ordinary skill in the art would not be able to ascertain the infectious disease(s) encompassed by the claims. Applicants respectfully traverse both rejections.

Applicants submit that, based on Applicants' disclosure, the phrase "(c) corresponding enzymes and prodrug substrates" would be understood by one skilled in the art to indicate that an enzyme and prodrug substrate are capable of forming a binding pair, as set forth in claim 38. At page 19, lines 16-21, Applicants' disclosure identifies prodrugs as the inactive precursor of a therapeutic agent, and states that a prodrug can function as the complementary member of a binding pair because it is the substrate for an enzyme, which is the other member of the binding pair. In light of this distinct disclosure, Applicants respectfully submit that the allegedly objectionable term is clear and definite, and withdrawal of the rejection of claim 38 respectfully is requested.

Applicants further submit that one skilled in the art would understand that the infectious diseases encompassed by independent claims 1, 37 and 38 may include any bacterial, viral or fungal infection for which a patient would benefit from the targeted delivery of the systemic therapy. Nevertheless, without acquiescing in any way in the propriety of the rejection, Applicants have amended claims 1, 37, and 38 to specifically remove the recitation of infectious disease causing agents, thereby mooting the rejection. Accordingly, withdrawal of the rejection of claims 1-42, 44, and 46-54 respectfully is requested.

Rejections for Obviousness-Type Double Patenting

Without acquiescing in the legal correctness of the rejections of claims 1, 25, and 26 based upon the doctrine of obviousness-type double patenting, Applicants herewith file a terminal disclaimer of claims 1, 25, and 26 over the term of U.S. Patent No. 5,736,119.

Without acquiescing in the legal correctness of the rejections of claims 37-40 based upon the doctrine of obviousness-type double patenting, Applicants herewith file a terminal disclaimer of claims 37-40 over the term of U.S. Patent No. 5,846,741.

Without acquiescing in the legal correctness of the rejections of claims 1, 25 and 27 based upon the doctrine of obviousness-type double patenting, Applicants herewith file a terminal disclaimer of claims 1, 25 and 27 over the term of U.S. Patent No. 5,482,698.

Because Applicants have not received any notice of allowance for co-pending U.S. Patent Application No. 10/361,026, the merits of this provisional rejection need not be discussed at this time. See MPEP § 822.01. Applicants further submit that upon acceptance of the claims by the examiner, the provisional obviousness-type double patenting rejection should be withdrawn.

In view of the terminal disclaimer herewith filed, withdrawal of the obviousness-type double patenting rejections respectfully is requested.

CONCLUSION

In view of the above remarks and amendments, it is respectfully submitted that this application is in condition for allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to telephone the undersigned at the number listed below if the Examiner believes such would be helpful in advancing the application to issue.

If any additional fees are required for the filing of this paper, Applicants authorize the Commissioner to charge any deficiency to Deposit Account No. 08-1641.

Respectfully submitted,

Date: August 12, 2004

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